

REMARKS

The above-identified patent application has been reviewed in light of the Final Office Action dated August 22, 2006. Claims 1, 8 and 18 have been amended, without intending to abandon or to dedicate to the public any patentable subject matter. Accordingly, Claims 1-15 and 18 are now pending. As set forth herein, reconsideration and withdrawal of the rejections of the claims are respectfully requested.

Initially, the Applicant would like to thank the Examiner for the courtesies extended during the telephone interview that was held between the Examiner and the undersigned on January 7, 2007. During that telephone interview, potential amendments to the claims to further distinguish the cited reference were discussed. In particular, specifying that the recited inner housing was in contact with components moved by that inner housing were discussed as a way to distinguish the claimed invention from the cited reference. No final agreement regarding allowable subject matter was reached.

Claims 1-15 and 18 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,478,316 to Bitdinger et al. ("Bitdinger"). Claim 9 stands rejected under 35 U.S.C. § 103 as being obvious over Bitdinger. However, all of the claimed elements cannot be found in the Bitdinger reference. Accordingly, reconsideration and withdrawal of the rejections of the claims as anticipated by or obvious in view of the Bitdinger reference are respectfully requested.

The present invention is generally directed to an injection device with a retractable needle. In particular, as set forth in the pending claims, the injection device features an inner housing that is configured to perform a number of different functions during operation and use of the injection device. As will be explained in detail herein, the Bitdinger reference does not teach, suggest or describe an injection device with an inner housing as set forth in the pending claims. Moreover, the Bitdinger reference does not teach, suggest or describe an injection device with components configured to operate in the same way as the claimed invention.

The Bitdinger reference is generally directed to an automatic self-injection device. The device includes a rod 46 that is coupled to a driver 58 in a storage position and up to a point

immediately following penetration of a user's skin by the needle 38. Initially, in the injection sequence of Bitdinger, the driver 58 and the rod 46 move as a unit under the constant force of the spring 56 causing the syringe assembly via the plug 24 to move forwardly. The rod remains coupled to the driver, and therefore the piston 32 does not move. (Bitdinger column 5, line 60 to column 6, line 1; Fig. 6.) The driver 58 and the rod 46 are then decoupled, allowing the rod to move with respect to the driver 58 and urging the piston 32 forwardly to displace fluid from the cartridge 30. (Bitdinger column 6, lines 5-12; Fig. 7.) After injection and removal of the device from the body, a sleeve 28 moves forwardly under the force of the sleeve spring to cover the needle 38. (Bitdinger, column 6, lines 22-25; Fig. 8.)

In applying Bitdinger to the claimed invention, the Office Action equates the sleeve 28 of Bitdinger with the inner housing recited in the pending claims. However, the sleeve 28 of Bitdinger does not include any structure or perform any function with respect to contacting or engaging the barrel of a syringe to move the barrel and a plunger axially, contacting or engaging the plunger and moving the plunger axially to expel medicament through the needle, or allowing the plunger and barrel to retract by acting on neither the plunger nor the barrel, or alternatively by disengaging from the barrel and the plunger. Moreover, the rod 46 of Bitdinger does not comprise an inner housing intermediate the outer housing and the barrel and the plunger as claimed. Instead, it is an elongate member that travels through the interior of the Bitdinger device including through a hole 24A through the plug 24 such that the rod 46 can access the interior of the cartridge to act on the piston 32 and to push the piston 32 down through the interior of the cartridge 30. In addition, Bitdinger does not teach, suggest or describe a mode or condition in which the rod 46 is disengaged from both a plunger and a barrel. Therefore, for at least these reasons, the pending claims are not anticipated by or obvious in view of Bitdinger and the rejections of the claims should be reconsidered and withdrawn.

Accordingly, the following elements of the independent claims indicated by italicized text cannot be found in the cited references:

1. (Currently Amended) An injection device, comprising:
an outer housing inside which is located:

a barrel for holding a dose of a medicament;

a needle at one end the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing;

a plunger, axially moveable within the barrel;

an inner housing intermediate the outer housing and the barrel and plunger; and

an energy source in communication with said inner housing,

wherein the inner housing is moveable by the energy source and operates in three modes, namely

a first mode in which *the inner housing is in contact with and acts on the barrel such that, in use, the plunger and barrel move axially* so as to move at least part of said needle out of the outer housing;

a second mode in which *the inner housing is in contact with and acts on the plunger to move the plunger axially but not the barrel* such that, in use, said plunger moves axially into said barrel so as to expel medicament through the needle; and

a third mode in which *the inner housing acts on neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract* in order to retract the needle into the outer housing.

18. (Currently Amended) A method of delivering an injection, comprising:
providing an injection device comprising:

a barrel for holding a dose of a medicament;

a needle at one end the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of a outer housing but is biased to be normally wholly inside the outer housing;

a plunger, axially moveable within the barrel;

an inner housing intermediate the outer housing and the barrel and plunger; and

an energy source which acts on the inner housing;

activating the energy source;

engaging the barrel with the inner housing and moving the barrel and the plunger axially in a first direction by means of the inner housing, wherein at least a part of the needle is moved out of the outer housing;

after moving the barrel and the plunger axially in the first direction, preventing further axial movement of the barrel in the first direction while engaging the plunger with the inner housing and moving the plunger axially in the first direction by means of the inner housing, wherein the plunger moves into the barrel causing medicament to be expelled through the needle;

after causing medicament to be expelled through the needle, disengaging the inner housing from the barrel and the plunger and retracting the needle into its biased position wholly inside the outer housing.

Therefore, at least with respect to pending Claim 1, Bitdinger does not teach, suggest or describe an inner housing intermediate the outer housing and the barrel and plunger that is moveable by the energy source and that is in contact with and acts on the barrel such that, in use, the plunger and barrel move axially so as to move at least part of the needle out of the outer housing. Instead, the inner housing 28 of Bitdinger simply acts to move a projection so that a push button can be activated when the inner housing 28 is moved rearwardly by being pressed against the patient's skin. (Bitdinger, column 5, lines 51-59; Fig. 7.) Bitdinger also does not describe a second mode in which the inner housing is in contact with and acts on the plunger to move the plunger axially but not the barrel so as to expel medicament through the needle. Instead, according to Bitdinger, after the needle has penetrated the skin, the driver 58 is decoupled from the rod 46 and the rod 46 moves with respect to the driver 58 to urge the piston 32 to displace fluid from the cartridge 30. (Bitdinger, column 6, lines 1-12.) In doing so, the rod 46 advances through an opening 24a in the plug 24. (Bitdinger, column 6, lines 13-14; Fig. 7.) Accordingly, the rod 46 of Bitdinger is entirely different from the claimed inner housing. Bitdinger also does not teach, suggest or describe a third mode in which the inner housing acts on neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract into the outer housing. The inner housing 28 of Bitdinger acts on neither the plunger nor the barrel. In addition, the Bitdinger device does not feature a needle that can be retracted into the outer

housing. Instead, the inner housing 28 springs forward to cover the needle as the device is withdrawn from the body. (Bitdinger, column 6, lines 22-25: Fig. 8.) Also, the rod 46 of Bitdinger never disengages from the plunger and the barrel. Accordingly, the Bitdinger reference does not disclose each of the elements of Claim 1 and the claims dependent therefrom, and therefore the rejections of Claims 1-15 should be reconsidered and withdrawn.

In addition, it is noted that at least some of the dependent claims recite additional patentable subject matter. For example, Claim 2 recites that the inner housing includes one or more flexible tags, biased radially inwardly by communication with the outer housing. The Office Action variously cites to component numbers 58, 24, 56, 66, 46 and 12 as being related to such tags. These components are described by Bitdinger in turn as a driver 58, a plug 24, a spring 56, a push button 66, a rod 46 and a housing 12. None of these components are part of an inner housing that are further biased radially inwardly by communication with the outer housing. Moreover, applicant notes that the driver 58 includes a pivotable arm 62 that is tipped up by a projection 70 of the outer housing when the driver 58 has moved forwardly with the syringe assembly 20. However, this component is tipped up by hitting the projection, and is not in any configuration of the Bitdinger device biased radially inwardly. Moreover, the pivotable arm is not part of the inner housing. Therefore, for at least these additional reasons, Claim 2 and Claims 3-8, which depend from Claim 2, are not taught, suggested or described by Bitdinger, and rejections of these claims should be reconsidered and withdrawn.

As a further example, Claim 10 recites that the injection device further includes means for allowing the inner housing to move axially only forward with respect to the outer housing. The Office Action cites to serration 53 of Bitdinger. Initially, it is noted that there are no serrations or reference number 53 included in the disclosure of Bitdinger. To the extent that the reference is to the notches 52 formed in the rod 46, it is noted that those notches are configured so that one of them receives an inwardly extending pawl 60 to prevent forward movement of the rod 46 independently of the driver 58 until the needle has penetrated the skin. (Bitdinger, column 6, lines 1-7: Figs. 5-7.) Moreover, the ramps of the notches are facing the wrong direction to stop forward movement of the rod. Therefore, for at least this additional reason,


Claim 10 and Claim 11, which depends from Claim 10, are not unpatentable in view of Bitdinger, and the rejections of these claims should be reconsidered and withdrawn.

With respect to independent Claim 18, as previously noted with respect to Claim 1, Bitdinger does not teach, suggest or describe an inner housing intermediate the outer housing and the barrel and plunger. In addition, Bitdinger does not discuss engaging the barrel with the inner housing and moving the barrel and plunger axially in a first direction by means of the inner housing. Instead, the inner housing of Bitdinger does not act on the barrel and plunger and the rod and driver of Bitdinger do not comprise an inner housing. Similarly, Bitdinger does not describe an inner housing that engages the plunger to move the plunger axially in the first direction. The Bitdinger reference also does not teach, suggest or describe a device having an inner housing that, after causing medicament to be expelled through the needle, disengages from the barrel and the plunger, and retracting the needle into its biased position wholly inside the outer housing. Therefore, the rejection of Claim 18 should be reconsidered and withdrawn.

As discussed herein, the Bitdinger reference does not teach, suggest or describe each and every element set forth in the pending claims. Accordingly, early notification of allowance is respectfully requested. The Examiner is invited to contact the undersigned by telephone if doing so would expedite resolution of this case.

Respectfully submitted,

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